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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,276	12/10/2001	Hiroyuki Hisamichi	Q67050	6088

7590 09/10/2003  
Sughrue Mion Zinn Macpeak & Seas  
2100 Pennsylvania Avenue N W  
Washington, DC 20037

EXAMINER

PATEL, SUDHAKER B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/009,276

Applicant(s)

HISAMICHI ET AL.

Examiner

Sudhaker B. Patel, D.Sc.Tech.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1,6.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Because applicants did not distinctly and specifically point out the supposed errors in the restriction/election requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

Applicants have elected ***without traverse*** invention of a Group, Claims (in part) 1-6, drawn to compounds, simple compositions, and a method of use of Formula (I) of claim 1 and the species wherein X is  $-NR_4$  and Y is  $-CR_7 = N-$ , forming a 1,4-diazine i.e. pyrazine core (see interview summary). Since claims 1-6 link with various inventions, this application will be examined bearing in mind the subject matter of invention of species of Group (6), and species wherein the core is 1,4-diazine (= pyrazine) as elected only by the applicants wide their communication paper # 10 dated 7/24/03 as mentioned above.

The requirement for restriction/election is still considered proper, and is therefore made FINAL.

### ***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted on 12/10/01 & 10/21/02 as the examiner respectively is considering papers # 1 & 6. Signed copies of the PTO Forms 1449 are enclosed with this communication for applicants' record.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 1-5,6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply.

4. Claim 1 recites A component as: " Arylene". It is not clear as to what exactly applicants want to claim. Is it 6-membered ring with 1, or 2 or 3 double bond(s) or Benzene ring-CH = CH<sub>2</sub>?

5. Claim 1 recites component R2 as: " -(CH =CH-CH =CH)-". Note R2 is a substituent onto the phenyl ring. Therefore, the valence of end carbon atom is not fully satisfied. Correction is required.

6. Claim 1 recites A component as: " heteroarylene which may have substituents". The nature of heteroarylene i.e. nature and number of heteroatoms(s), size of the ring, number of ring(s), and the exact point of contact with carbon atom(s) (where applicable) on either sides of -A- are not disclosed. Therefore, it is very difficult to interpret the claim as recited.

7. Claim 1 recites R3 as: "-(NH<sub>2</sub> in a prodrug form)". It is not clear as to whether both of the H atoms are involved in this form or only one H atom or none wherein -NH<sub>3</sub><sup>+</sup> salt is formed.

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Claims 2- 6 recite: " a salt thereof". Correction to: " a pharmaceutically acceptable salt is required.

### ***Conclusion***

#### ***Allowable Subject Matter***

8. Claims 1-6 related to invention of a group of compounds of Formula (I) wherein X is  $-NR_4$  and Y is  $-CR_7 = N-$ , forming a 1,4-diazine i.e. pyrazine core = Group (6) would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph and others where applicable, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: The closest prior art of record reference Davis et al( WO 9818782) teaches 2-pyrimidine derivatives and their utility as tyrosine kinase syk inhibitors.

10. The reference does not indicate or suggest to arrive at the instant compounds having  $-Y = Z-$  as  $-CR_7 = N-$ , thus forming 1,4-diazine core wherein 2-position is occupied by  $-NR_1$ -phenyl; 3-position by  $-CONH_2$ ; 5-position by  $-C(R_7)-$ , and 6-position by  $-X-A-R_3$  respectively.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker B. Patel, D.Sc.Tech. whose telephone number is 703 308 4709. The examiner can normally be reached on 6:30 to 5:00 pm (Monday-Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund J. Shah can be reached on 703 308 4716 or Sr. Examiner Mr. Richard Raymond at (703) 308 4523.


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The fax phone numbers for the organization where this application or proceeding is assigned are 703 308 4556 for regular communications and 703 308 4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 1235.



Sudhaker B. Patel, D.Sc.Tech.  
September 5, 2003.



MUKUND SHAH  
SUPERVISORY PATENT  
EXAMINER  
ART UNIT 1624